DEC 2 1 2011

Section 11. 510(k) Summary

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) number is: K112274

1. Submitter's Identification:
   TaiDoc Technology Corporation
   3F, 5F, No.127, Wugong 2nd Rd., Wugu District, New Taipei City, 24888, Taiwan

   Correspondence:
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   Regulatory Affairs Specialist
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   Date of submission: 08/05/2011

2. Device name:
   Proprietary name: U-RIGHT TD-3135 Blood Pressure Monitoring System

   Regulatory information:

   A. Regulation section: 21 CFR §870.1130, Noninvasive blood pressure measurement system
   B. Classification: Class II (Blood Pressure Measurement System)
   C. Product Code: DXN, System, Measurement, Blood-Pressure, Non-Invasive
   D. Panel: 74, Cardiovascular – Blood Pressure Measurement System

3. Intended Use:

The U-RIGHT TD-3135 Blood Pressure Monitoring System is intended to be used to measure the systolic and diastolic blood pressure and pulse rate by using a non-invasive technique in which an inflatable cuff is wrapped on the upper arm. This system should only be used for the testing on people over 18 years of age and over.

4. Device Description:

The kit of U-RIGHT TD-3135 Blood Pressure Monitoring System consists of two main products: the Blood Pressure Monitor and the pressure cuff. The product has been designed and tested to work together as a system to produce accurate blood pressure measurements.

5. Substantial Equivalence Information:

A. Predicate device name:

FORA P20/U-RIGHT TD-3132 Blood Pressure Monitoring System

B. Predicate K number: K092106

C. Comparison with predicate:

The modified U-RIGHT TD-3135 Blood Pressure Monitoring System has the following similarities to the predicate device:

- same operating principle,
- same fundamental scientific technology,
- incorporate the same basic circuit design,
- incorporate the same materials,
- same shelf life
- packaged using the same materials, and
- manufactured by the same process.

The modifications encompass:

- Modification of the devices physical appearance
- Decreased memory storage capacity
- Removed the data transmission function
- Labeling change due to the above modifications

6. Test Principle:

The measurement is by using oscillometric, non-invasive blood pressure (systolic, diastolic blood pressure and pulse rate) measuring technology.

7. Performance Characteristics:

The U-RIGHT TD-3135 Blood Pressure Monitoring System has the same performance characteristics as the predicate device.

Software verification and validation, and design validation confirmed that the performance, safety and effectiveness of the U-RIGHT TD-3135 Blood Pressure Monitoring System are equivalent to the predicate device.

8. Conclusion:

Based on the information provided in this submission, the U-RIGHT TD-3135 Blood Pressure Monitoring System is substantially equivalent to the predicate FORA P20/U-RIGHT TD-3132 Blood Pressure Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 2 1 2011

TaiDoc Technology Corporation
c/o Ms. Linda Ko
Regulatory Affairs Specialist
6F, No. 127, Wugong 2nd Rd.
Wugu Township, New Taipei City
TAIWAN 24888

Re: K112274
Trade/Device Names: TaiDoc U-RIGHT TD-3135 Blood Pressure Monitoring System
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: November 30, 2011
Received: December 1, 2011

Dear Ms. Ko:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark Kellman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 8.

Indications for Use

510(k) Number: K112274

Device Name: U-RIGHT TD-3135 Blood Pressure Monitoring System

Indications for Use:

The U-RIGHT TD-3135 Blood Pressure Monitoring System is intended to be used to measure the systolic and diastolic blood pressure and pulse rate by using a non-invasive technique in which an inflatable cuff is wrapped on the upper arm. This system should only be used for the testing on people over 18 years of age and over.

Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use __X__. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Bram Zuckerman

Division Sign-Off Director DCD

Office of Device Evaluation (ODE)

510(k) K112274